

1 **CATHETER HAVING CIRCULAR ABLATION ASSEMBLY**

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of Application Serial No. 10/118,680, filed

5 April 9, 2002, titled CATHETER HAVING CIRCULAR ABLATION ASSEMBLY, which claims the benefit of U.S. Provisional Patent Application No. 60/360,431, filed February 28, 2002, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

10 The resent invention relates to an improved ablation catheter that is particularly useful for ablating in a tubular region of or near the heart.

BACKGROUND OF THE INVENTION

Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke.

15 This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. A common procedure involves ablating a lesion to interrupt the wavelets using one or more electrodes mounted on the distal end of a generally-straight catheter. This procedure works well, for example, when ablating a line of block in the atria. However, for 20 tubular regions in or around the heart, this procedure is less effective. For example, when the line of block is to be made about a circumference of the tubular region, it is difficult to manipulate and control the distal end of a straight catheter so that it effectively ablates about the circumference. Accordingly, a need exists for an improved catheter that is particularly useful for such applications.

25

SUMMARY OF THE INVENTION

The present invention is directed to a catheter having a generally-circular ablation assembly mounted on its distal end that carries a tip electrode. In one embodiment, the catheter comprises an elongated flexible tubular catheter body having an axis and proximal and distal ends. An ablation assembly is mounted at the distal end of the tubular body. The ablation

1 assembly has a preformed generally circular curve that is generally transverse to the axis of the catheter body comprising a flexible tubing having proximal and distal ends and carrying a tip electrode at its distal end. An electrode lead wire extends through the catheter body and into the ablation assembly and has a distal end connected to the tip electrode.

5 In use, the distal end of the catheter is inserted into the heart of a patient. At least a portion of the outer circumference of the generally circular curve is contacted with the inner circumference of the tubular region so that the tip electrode is in a first position in contact with tissue along the inner circumference. The tip electrode is used to ablate tissue at the first position. The ablation assembly can then be rotated so that the tip electrode is in a second position in contact with tissue along the inner circumference different from the first position, and the tip electrode is used to ablate tissue at the second position. This procedure can be repeated to form a lesion of the desired length along the inner circumference. This design permits the user to have more control when ablating about a circumference of a tubular region in or around the heart, e.g., a pulmonary vein, the coronary sinus, the superior vena cava, or the pulmonary outflow tract.

10

15

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of an embodiment of the catheter of the invention;

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and the intermediate section;

FIG. 3 is a side cross-sectional view of the intermediate section, including the junction between the intermediate section and the ablation assembly;

FIG. 4 is a schematic perspective view of an ablation assembly according to the invention;

FIG. 5 is a schematic perspective view of an alternative ablation assembly according to the invention;

30 FIG. 6 is a side view of the ablation assembly of FIG. 5;

1 FIG. 7 is a side cross-sectional view of the distal end of an ablation assembly according to the invention; and

FIG. 8 is a perspective view of an alternative tip electrode according to the invention.

5 **DETAILED DESCRIPTION**

In a particularly preferred embodiment of the invention, there is provided a catheter having an ablation assembly at its distal end. As shown in FIG. 1, the catheter comprises an elongated catheter body 12 having proximal and distal ends, an intermediate section 14 at the distal end of the catheter body, a control handle 16 at the proximal end of the catheter body, and 10 an ablation assembly 17 mounted at the distal end of the catheter to the intermediate section.

With reference to FIG. 2, the catheter body 12 comprises an elongated tubular construction having a single, axial or central lumen 18. The catheter body 12 is flexible, i.e. bendable, but substantially non-compressible along its length. The catheter body 12 can be of any suitable construction and made of any suitable material. A presently preferred construction 15 comprises an outer wall 20 made of polyurethane or PEBAX. The outer wall 20 comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body 12 so that, when the control handle 16 is rotated, the intermediate section 14 of the catheter 10 will rotate in a corresponding manner.

The outer diameter of the catheter body 12 is not critical, but is preferably no more than 20 about 8 french, more preferably about 7 french. Likewise, the thickness of the outer wall 20 is not critical, but is thin enough so that the central lumen 18 can accommodate a puller wire, one or more lead wires, and any other desired wires, cables or tubes. If desired the inner surface of the outer wall 20 is lined with a stiffening tube (not shown) to provide improved torsional stability. A particularly preferred catheter has an outer wall 20 with an outer diameter of from 25 about 0.090 inch to about 0.94 inch and an inner diameter of from about 0.061 inch to about 0.065 inch.

The intermediate section 14 comprises a short section of tubing 22 having three lumens. The first lumen 30 carries one or more lead wires 50 or other wires discussed further below, the second lumen 32 carries a puller wire 64, and the third lumen 34 carries a support member 24. 30 The tubing 22 is made of a suitable non-toxic material that is preferably more flexible than the

1 catheter body **12**. A presently preferred material for the tubing **22** is braided polyurethane, i.e. polyurethane with an embedded mesh of braided stainless steel or the like. The size of each lumen is not critical, but is sufficient to house the lead wires, puller wire or support member.

5 The useful length of the catheter, i.e. that portion that can be inserted into the body excluding the ablation assembly **17**, can vary as desired. Preferably, the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably from about 5 cm to about 6.5 cm.

10 A preferred means for attaching the catheter body **12** to the intermediate section **14** is illustrated in FIG. 2. The proximal end of the intermediate section **14** comprises an outer circumferential notch **26** that receives the inner surface of the outer wall **22** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like.

15 If desired, a spacer (not shown) can be located within the catheter body between the distal end of the stiffening tube (if provided) and the proximal end of the intermediate section. The spacer provides a transition in flexibility at the junction of the catheter body and intermediate section, which allows this junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Patent No. 5,964,757, the disclosure of which is incorporated herein by reference.

20 At the distal end of the intermediate section **14** is the ablation assembly **17**, as shown in FIGs. 3 to 7. In the depicted embodiment, the ablation assembly **17** comprises the distal end of the support member **24** covered by a non-conductive covering **28**. In the embodiment of FIG. 4, the ablation assembly **17** comprises a generally straight proximal region **38** and a generally circular main region **39** that is generally transverse to the catheter body. The proximal region **38** is mounted on the intermediate section **14**, as described in more detail below, so that its axis is generally parallel to the axis of the intermediate section. In this embodiment, the proximal region **38** is generally at the center of the generally circular main region **39**. The proximal region **38** preferably has an exposed length, i.e. not contained within the intermediate section **14**, ranging from about 3 mm to about 12 mm, more preferably about 3 mm to about 8 mm, still more preferably about 5 mm, but can vary as desired.

1 The generally circular main region **39** does not have to form a complete circle, but should
be at least about 180°, e.g. a semi-circle, more preferably at least about 270°, still more
preferably at least about 320°. In the preferred embodiment, the generally circular main region
5 **39** forms at least a complete circle, e.g. is at least 360°. If desired, the generally circular main
region can comprise more than one loop or circle, so that it has, for example, a spiral or conical
shape. The generally circular main region **39** is generally transverse to the catheter body **12** and
intermediate section **14**, and preferably forms an angle with the catheter body ranging from about
80° to about 100°, more preferably about 90°. The generally circular main region **39** has an
outer diameter preferably ranging from about 2 mm to about 40 mm, more preferably from about
10 10 mm to about 25 mm, still more preferably from about 12 mm to about 20 mm, even more
preferably about 15 mm.

15 In an alternative embodiment, as shown in FIGs. 5 and 6, the ablation assembly **17**
further comprises a generally straight distal region **40** that extends beyond the generally circular
main region **39**. In this embodiment, the proximal region **38** is at the side of the generally
circular main region **39**, as best shown in FIG. 6.

20 The support member **24** is made of a material having shape-memory, i.e. that can be
straightened or bent out of its original shape upon exertion of a force and is capable of
substantially returning to its original shape upon removal of the force. A particularly preferred
material for the support member is a nickel/titanium alloy. Such alloys typically comprise about
25 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the
balance being titanium. A preferred nickel/titanium alloy is nitinol, which has excellent shape
memory, together with ductility, strength, corrosion resistance, electrical resistivity and
temperature stability. The non-conductive covering **28** can be made of any suitable material, and
is preferably made of a biocompatible plastic such as polyurethane or PEBAX. If desired, the
support member **24** can be eliminated and the distal end of the non-conductive covering **28** can
be pre-formed to have the desired curve of the ablation assembly.

30 A tip electrode **35** is mounted at the distal end of the ablation assembly **17** for ablating
tissue. As shown in FIG. 7, the tip electrode **35** has an exposed region **35a** and a stem **35b** that
extends into the non-conductive covering **28**. In the embodiment of FIG. 7, the tip electrode **35**

1 has a generally cylindrical exposed region **35a** with an outer diameter approximately the same as
the outer diameter of the non-conductive covering **28** by polyurethane glue or the like.

5 In an alternative embodiment, as shown in FIG. 8, the exposed region **35a** of the tip
electrode has a bulb shape with a varying outer diameter wherein at least a portion of the
exposed region extends beyond the outer circumference of the non-conductive covering **28**. It
has been found that a catheter having a bulb-shaped tip electrode can provide better contact with
the tissue based on the outward spring-like force exerted by the generally circular ablation
assembly. Other tip electrode shapes will be apparent to one skilled in the art. For example, an
10 asymmetrical tip electrode (not shown) could be provided where the side of the electrode that
would be in contact with the tissue, i.e. on the outside of the ablation assembly, extends beyond
the outer wall of the non-conductive covering **28** and the inner side of the tip electrode is
generally even with the wall of the non-conductive covering.

15 An electrode lead wire **50** connects the tip electrode **35** to a suitable source of ablation
energy (not shown), preferably radio frequency (RF) energy. The distal end of the lead wire **50**
is soldered in a first blind hole **51** in the proximal end of the tip electrode **35**. The lead wire **50**
extends between the non-conductive covering **28** and the support member **24**. The proximal end
of the lead wire **50** is electrically connected to a suitable connector **37**, which is connected to the
source of ablation energy as is known in the art. The lead wire **50** extends through the first
lumen **30** of the intermediate section **14**, the central lumen **18** of the catheter body **12**, and the
20 control handle **16**, and terminates at its proximal end in the connector **37**. In the depicted
embodiment, the portion of the lead wire **50** extending through the central lumen **18** of the
catheter body **12**, control handle **16** and proximal end of the intermediate section **14** is enclosed
within a protective sheath **62** to prevent contact with other components within the lumen of the
catheter body and in the handle. The protective sheath **62** can be made of any suitable material,
25 preferably polyimide. The protective sheath **62** is anchored at its distal end to the proximal end
of the intermediate section **14** by gluing it in the first lumen **30** with polyurethane glue or the
like. As would be recognized by one skilled in the art, the protective sheath can be eliminated if
desired.

30 A temperature sensor is provided for monitoring the temperature of the tip electrode **35**.
Any conventional temperature sensor, e.g. a thermocouple or thermistor, may be used. In the

1 embodiment shown in FIG. 7, the temperature sensor comprises a thermocouple formed by an
enamed wire pair. One wire of the wire pair is a copper wire 53, e.g. a number 40 copper wire.
The other wire of the wire pair is a constantan wire 54. The wire 53 and 54 of the wire pair are
electrically isolated from each other except at their distal ends where they are twisted together,
5 covered with a short piece of plastic tubing 55, e.g. polyimide, and covered with epoxy. The
plastic tubing 55 is then attached in a second blind hole 56 of the tip electrode 35, by
polyurethane glue or the like. Alternatively, the wires 53 and 54 can be soldered into the second
blind hole 56 or otherwise attached to the tip electrode 35. The wires 53 and 54 extend through
the first lumen 30 in the intermediate section 14 and through the central lumen 18 of the catheter
10 body 12 along with the lead wire 50. The wires 53 and 54 then extend out through the control
handle 16 and to a connector (not shown) connectable to a temperature monitor (not shown).
Preferably, the wires 53 and 54 extend through the protective sheath 62 in the catheter body 12.

Additionally, a safety wire 57 is provided to further secure the tip electrode 35 to the
ablation assembly 17 and assure that the tip electrode does not fall off in the patient's body. The
15 safety wire is preferably a metal wire having its distal end soldered in a third blind hole 58 in the
tip electrode 35 and its proximal end soldered or otherwise attached in the control handle 126. In
the depicted embodiment, the safety wire 57 extends through the first lumen 30 in the
intermediate section 14 and through the central lumen 18 of the catheter body 12 along with the
lead wires 50 and thermocouple wires 53 and 54. Other arrangements for attaching the safety
20 wire can be provided, as would be recognized by one skilled in the art, or the safety wire can be
eliminated.

If desired, one or more ring electrodes (not shown) can be mounted on the non-
conductive covering 28 of the generally circular main region 39 of the ablation assembly 17.
Such ring electrodes might be desirable, for example, for mapping the region to be ablated before
25 ablation begins or after ablation to assure that the lesions blocked the electrical activity as
desired. A description of a catheter including such ring electrodes is described in U.S. Patent
Application No. 09/551,467, entitled "Catheter Having Mapping Assembly," the entire
disclosure of which is incorporated herein by reference. If desired, additional ring electrodes
30 (not shown) could be mounted elsewhere along the ablation assembly 17 and/or intermediate
section 14.

1 The junction of the intermediate section **14** and ablation assembly **17** is shown in FIG. 3. The non-conductive covering **28** is attached to the tubing **22** of the intermediate section by glue or the like. The support member **24** extends from the third lumen **34** into the non-conductive covering **28**. The proximal end of the support member **24** terminates a short distance within the
5 third lumen **34**, approximately 5 mm, so as not to adversely affect the ability of the intermediate section **14** to deflect. However, if desired, the proximal end of the support member **24** can extend into the catheter body **12**.

10 The lead wires **50**, thermocouple wires **53** and **54** and safety wire **57** extend through the first lumen **30** of the intermediate section **14**, through the central lumen **18** of the catheter body
12, and the control handle **16**, and terminate at their proximal end in the connector **37**. As noted above, the portion of the wires extending through the central lumen **18** of the catheter body **12**, control handle **16** and proximal end of the intermediate section **14** are enclosed within a protective sheath **62**, which can be made of any suitable material, preferably polyimide. The protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section
15 **14** by gluing it in the first lumen **30** with polyurethane glue or the like.

20 The puller wire **64** is provided for deflection of the intermediate section **14**. The puller wire **64** extends through the catheter body **12**, is anchored at its proximal end to the control handle **16**, and is anchored at its distal end to the intermediate section **14**. The puller wire **64** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **64**. The puller wire **64** preferably has a diameter ranging from about 0.006 to about 0.010 inch.

25 A compression coil **66** is situated within the catheter body **12** in surrounding relation to the puller wire **64**, as shown in FIG. 2. The compression coil **66** extends from the proximal end of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coil
66 is made of any suitable metal, preferably stainless steel. The compression coil **66** is tightly wound on itself to provide flexibility, i.e. bending, but to resist compression. The inner diameter of the compression coil **66** is preferably slightly larger than the diameter of the puller wire **64**. The Teflon® coating on the puller wire **64** allows it to slide freely within the compression coil **66**. The outer surface of the compression coil is covered by a flexible, non-conductive sheath **58**, e.g.
30 made of polyimide tubing.

1 The compression coil **66** is anchored at its proximal end to the outer wall **20** of the catheter body **12** by proximal glue joint **70** and at its distal end to the intermediate section **14** by distal glue joint **72**. Both glue joints **70** and **72** preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the 5 outer surface of the catheter body **12** and the central lumen **18**. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall **20** of the catheter body **12** which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **66** and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil.

10 The puller wire **64** extends into the second lumen **32** of the intermediate section **14**. Preferably, the puller wire **64** is anchored at its distal end to the distal end of the intermediate section **14**, as shown in FIG. 3. Specifically, a T-shaped anchor is formed, which comprises a short piece of tubular stainless steel **80**, e.g. hypodermic stock, which is fitted over the distal end of the puller wire **64** and crimped to fixedly secure it to the puller wire. The distal end of the 15 tubular stainless steel **80** is fixedly attached, e.g. by welding, to a cross-piece **82** formed of stainless steel ribbon or the like. The cross-piece **82** sits beyond the distal end of the second lumen **32**. The cross-piece **82** is larger than the lumen opening and, therefore, cannot be pulled through the opening. The distal end of the second lumen **32** is then filled with glue or the like, preferably polyurethane glue. Within the second lumen **32** of the intermediate section **14**, the 20 puller wire **64** extends through a plastic, preferably Teflon®, puller wire sheath (not shown), which prevents the puller wire **64** from cutting into the wall of the intermediate section **14** when the intermediate section is deflected.

25 Longitudinal movement of the puller wire **64** relative to the catheter body **12**, which results in deflection of the intermediate section **14**, is accomplished by suitable manipulation of the control handle **16**. Examples of suitable control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502 and 5,897,529, the entire disclosures of which are incorporated herein by reference.

30 In use, a suitable guiding sheath is inserted into the patient with its distal end positioned at a desired mapping location. An example of a suitable guiding sheath for use in connection with the present invention is the Preface™ Braided Guiding Sheath, commercially available from

1 Biosense Webster, Inc. (Diamond Bar, California). The distal end of the sheath is guided into
one of the atria. A catheter in accordance with the present invention is fed through the guiding
sheath until its distal end extends out of the distal end of the guiding sheath. As the catheter is
fed through the guiding sheath, the ablation assembly **17** is straightened to fit through the sheath.
5 Once the distal end of the catheter is positioned at the desired mapping location, the guiding
sheath is pulled proximally, allowing the deflectable intermediate section **14** and ablation
assembly **17** to extend outside the sheath, and the ablation assembly **17** returns to its original
shape. The ablation assembly **17** is then inserted into a pulmonary vein or other tubular region
(such as the coronary sinus, superior vena cava, or inferior vena cava) so that the outer
10 circumference of the generally circular main region **39** of the assembly is in contact with a
circumference inside the tubular region and the tip electrode **35** is generally in contact with the
tissue.

The circular arrangement of the ablation assembly **17** provides a stable mechanism for
keeping the tip electrode **35** in a desired location for ablation. To ablate a circumferential lesion
15 in the tubular region, the user rotates the ablation assembly **17** by rotating the control handle **16**
and applies ablation energy through the tip electrode **35** at adjacent points along the
circumference. The design of the ablation assembly permits the user to more easily ablate about
a circumference compared to using a tip electrode on a straight catheter, where it is more
difficult to accurately move the tip electrode about the circumference of the tubular region.

20 As will be recognized by one skilled in the art, it is easier to turn the ablation assembly in
a direction such that the tip electrode is being pulled rather than pushed. For example, in the
embodiments depicted in FIGs. 4 and 5, where the ablation assemblies are formed in a clockwise
direction, it is preferable to turn the assemblies in a counterclockwise direction. Accordingly, if
desired, an arrow or other indicator (not shown) can be included on the handle or proximal end
25 of the catheter body to indicate to the user the preferred direction for rotating the ablation
assembly in the body.

If desired, two or more puller wires can be provided to enhance the ability to manipulate
the intermediate section. In such an embodiment, a second puller wire and a surrounding second
compression coil extend through the catheter body and into an additional off-axis lumen in the
30 intermediate section. The first puller wire is preferably anchored proximal to the anchor location

1 of the second puller wire. Suitable designs of catheters having two or more puller wires, including suitable control handles for such embodiments, are described, for example, in U.S. Patent Nos. 6,123,699, 6,171,277, 6,183,435, 6,183,463, 6,198,974, 6,210,407, and 6,267,746, the disclosures of which are incorporated herein by reference.

5 Alternatively, a second puller wire (not shown) can be included to alter the diameter of the distal end of the ablation assembly. Such an arrangement is generally described in U.S. Patent No. 5,626,136, the disclosure of which is incorporated herein by reference. The above-referenced control handles could be used to manipulate the second puller wire.

10 The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

15 Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fairest scope.

20

25

30